L Number	Hits	Search Text	DB	Time stamp
1	3	klee-george-g-.in.	USPAT; US-PGPUB	2003/08/26 14:09
2	158615	calibrat$3	USPAT; US-PGPUB	2003/08/26 14:09
3	7	calibrat$3 same (control adj pool$1)	USPAT; US-PGPUB	2003/08/26 14:11
4	17846	calibrat$3 same (analyzer$1 or instrument$1)	USPAT; US-PGPUB	2003/08/26 14:12
5	171	(calibrat$3 same (analyzer$1 or instrument$1)) same (tolerance)	USPAT; US-PGPUB	2003/08/26 14:12
6	18	((calibrat$3 same (analyzer$1 or instrument$1)) same (tolerance)) same limit$1	USPAT; US-PGPUB	2003/08/26 14:20
8	2859	(calibrat$3 same (analyzer$1 or instrument$1)) and (422/$.ccls. or 436/$.ccls. or 435/$.ccls.)	USPAT; US-PGPUB	2003/08/26 14:23
9	16	((calibrat$3 same (analyzer$1 or instrument$1)) and (422/$.ccls. or 436/$.ccls. or 435/$.ccls.)) and (tolerance adj limit$1)	USPAT; US-PGPUB	2003/08/26 14:32
10	124	calibrat$3 same (tolerance adj limit$1)	USPAT; US-PGPUB	2003/08/26 14:32
11	0	(calibrat$3 same (tolerance adj limit$1)) same pool$1	USPAT; US-PGPUB	2003/08/26 14:33
12	0	(control adj pool) adj data	USPAT; US-PGPUB	2003/08/26 14:33
13	15	(calibrat$3 same (tolerance adj limit$1)) and (422/$.ccls. or 436/$.ccls. or 435/$.ccls. or 702/$.ccls.)	USPAT; US-PGPUB	2003/08/26 14:35
14	14	((calibrat$3 same (tolerance adj limit$1)) and (422/$.ccls. or 436/$.ccls. or 435/$.ccls. or 702/$.ccls.)) not (((calibrat$3 same (analyzer$1 or instrument$1)) and (422/$.ccls. or 436/$.ccls. or 435/$.ccls.)) and (tolerance adj limit$1))	USPAT; US-PGPUB	2003/08/26 14:46
15	736	calibrat$3 and (tolerance adj limit$1)	USPAT; US-PGPUB	2003/08/26 14:46
16	56	(calibrat$3 and (tolerance adj limit$1)) and clinical	USPAT; US-PGPUB	2003/08/26 14:47
17	38	((calibrat$3 and (tolerance adj limit$1)) and clinical) and patient$1	USPAT; US-PGPUB	2003/08/26 14:47
18	12	(((calibrat$3 and (tolerance adj limit$1)) and clinical) and patient$1) and pool$3	USPAT; US-PGPUB	2003/08/26 14:47

WEST Search History

DATE: Tuesday, August 26, 2003

Set Name side by side	Query	Hit Count	Set Name result set
	DB=JPAB,EPAB,DWPI,TDBD; PLUR=YES; OP=ADJ		
L12	L11 and limit$1	6	L12
L11	l9 and tolerance	46	L11
L10	L9 and pool$1	4	L10
L9	l2 and (instrument$1 or analyzer$1)	5670	L9
L8	L7 and l2	1	L8
L7	control adj pool$1	67	L7
L6	l3 not l5	20	L6
L5	L3 and control$1	9	L5
L4	L3 and pool$1	0	L4
L3	L2 and (tolerance adj limit$1)	29	L3
L2	calibrat$3	68472	L2
L1	klee-g-$.in.	5	L1

d his

(FILE 'HOME' ENTERED AT 13:34:35 ON 26 AUG 2003)

FILE 'CAPLUS, CAOLD, MEDLINE, BIOSIS' ENTERED AT 13:35:13 ON 26 AUG 2003

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                E KLEE GEORGE G/AU
L1          124 S E3
L2            0 S L1 AND CALIBRAT?
L3            7 S L1 AND TOLERANCE
L4            3 DUP REMOV L3 (4 DUPLICATES REMOVED)
L5        24418 S CALIBRAT? AND (ANALYZER? OR INSTRUMENT?)
L6            0 S L5 AND CONTROL POOL
L7            5 S L5 AND CONTROL POOL?
L8            4 DUP REMOV L7 (1 DUPLICATE REMOVED)
L9            0 S CONTROL POOL DATA
L10          90 S CALIBRAT? AND TOLERANCE LIMIT?
L11           0 S L10 AND POOL?
L12          13 S L10 AND (ANALYZER? OR INSTRUMENT?)
L13          12 DUP REMOV L12 (1 DUPLICATE REMOVED)
                E KLEE GEORGE/AU
L14          29 S E3
L15           0 S L14 AND CALIBRAT?
L16           4 S L1 AND TOLERANCE LIMIT?
L17           2 DUP REMOV L16 (2 DUPLICATES REMOVED)
L18           0 S L1 AND CONTROL POOL?
L19           0 S L14 AND CONTROL POOL?
L20           2 S L14 AND TOLERANCE LIMIT?
L21           2 S L20 NOT L17
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L17 ANSWER 2 OF 2 CAPLUS COPYRIGHT 2003 ACS on STN DUPLICATE 2
AN 1993:577095 CAPLUS
DN 119:177095
TI **Tolerance limits** for short-term analytical bias and analytical imprecision derived from clinical assay specificity
AU **Klee, George G.**
CS Dep. Lab. Med. Pathol., Mayo Clin., Rochester, MN, 55905, USA
SO Clinical Chemistry (Washington, DC, United States) (1993), 39(7), 1514-18
CODEN: CLCHAU; ISSN: 0009-9147
DT Journal
LA English
AB A method is proposed for defining **tolerance limits** for assay bias and assay imprecision, based on the effects of these **tolerance limits** on the clin. specificity of the assay. An anal. "error budget" is defined as the squared sums of the imprecision and bias errors. The max. limit for this error budget is set at a value corresponding to a 50% increase in the false-pos. rate for classifying healthy subjects. For Gaussian distributions with .+-.2 SD used as decision limits, this error budget equates to 0.45 SD of combined within-person and between-person biol. variation (SDBiol). To provide reasonable power for bias detection in an assay, it is recommended that the SD of the assay be kept at less than half the bias limit. Then, for the Gaussian distribution, the max. bias limit should be <0.36 SDBiol and the SD of the assay should be <0.18 SDBiol. Procedures are provided for using the same principles to define **tolerance limits** for decision limits other than .+-.2 SD and for nongaussian distributions.

L21 ANSWER 2 OF 2 BIOSIS COPYRIGHT 2003 BIOLOGICAL ABSTRACTS INC. on STN
AN 1997:290959 BIOSIS
DN PREV199799590162
TI A conceptual model for establishing **tolerance limits** for analytic bias and imprecision based on variations in population test distributions.
AU **Klee, George**
CS 360 Hilton Building, Mayo Clinic, 200 First Street SW, Rochester, MN 55905 USA
SO Clinica Chimica Acta, (1997) Vol. 260, No. 2, pp. 175-188. ISSN: 0009-8981.
DT Journal; Article
LA English
AB A conceptual model is proposed for defining analytic bias limits utilizing the variations found in cumulative test value distributions. The model is based on the propositions that changes in analytic bias are more important than analytic imprecision in medical diagnoses and that analytic bias alters clinical specificity more than clinical sensitivity. The rationale for these propositions are presented along with a step-by-step procedure for estimating bias **tolerance limits**. These concepts are illustrated with an example using prostate-specific antigen. A second protocol is provided to define analytic imprecision **tolerance limits**, based on the quality control performance characteristics required to maintain the bias **tolerance limits**. This model can be applied to most chemistry, immunoassay, and hematologic quantitative assays. The relationship of this procedure to the published procedures using biologic variation for defining analytic **tolerance limits** is discussed.

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